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BROOKS, KRISTIE LATRICE				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/598,800

Applicant(s)

CLARKE, PAUL DOUGLAS

Examiner

KRISTIE L. BROOKS

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. Claims 23-42 are pending.
 2. Receipt and consideration of Applicants remarks filed on August 8, 2008 is acknowledged.
 3. Rejections not reiterated from the previous Office Action are hereby withdrawn.
- The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

New Ground of Rejection Necessitated by Applicant's Amendment

Claim Rejections - 35 USC § 112 1st

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for destroying, inactivating, or inhibiting the growth of some viruses such as influenza (i.e. A/Sydney/5/97), Herpes Simplex Virus-1, and Urbani SARS does not reasonably provide enablement for destroying, inactivating, or inhibiting the growth of **any and all** viruses, wherein the virus has a lipid envelope. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Scope or breadth of the claims

The scope of the claims is drawn to a method of using p-menthane-3,8-diol (PMD) to destroy, inactivate or inhibit growth or reproduction of any virus that contains a lipid envelope.

Nature of the invention

The nature of the invention is directed to a method of using p-menthane-3,8-diol (PMD) to destroy, inactivate or inhibit growth or reproduction of any virus that has a lipid envelope.

State of, or the amount of knowledge in, the prior art

There are many proposed treatments for viruses. Most treatments have distinct drugs that are used to treat only certain viruses. Such as interferon- α used to treat hepatitis and anti-retroviral drugs used to treat HIV-infection(Taiwo, Abstract, Antiretroviral treatment: current approach and future prospects, *African Journal of Medical Medicines and Science*, 35 Suppl: 1-11, 2006; Safren et al., Abstract, Strategies for primary HIV prevention that target behavioral change, *Clinical of Infectious diseases*, 45 Suppl 4:S300-307, 2007; Krastev, The "return "of hepatitis B, *World Journal of Gastroenterology*, 12(44):7081-7086, 2006)..

Level or degree of predictability, or a lack thereof, in the art

Claim 1 is directed to a method of using p-menthane-3,8-diol (PMD) to destroy, inactivate or inhibit growth or reproduction of any virus that has a lipid envelope. There is a seemingly infinite number of species of viruses that contain a lipid envelope. Many viruses use different distinct drugs designed specifically to target the viruses' mechanism to produce disease, such as interferon- α for Hepatitis B or anti-retroviral agents for HIV-infections. Further, there is no known drug to destroy viruses, such as HIV. There is no known drug capable of treating all viruses and thus there is a high level

of unpredictability as to whether p-menthane-3,8-diol is capable of destroying, inactivating or inhibiting growth or reproduction of all viruses that contain a lipid envelope.

Amount of guidance or direction provided by the inventor

The specification provides guidance on destroying, inactivating or inhibiting growth or reproduction of viruses such as A/Sydney/5/97, Herpes Simplex Virus-1, or Urbani SARS using PMD. However, the specification fails to provide guidance or direction on destroying, inactivating or inhibiting growth or reproduction of any other virus that has a lipid envelope.

Presence or absence of working examples

The specification provides examples of the virucidal activity of PMD on only three viruses, i.e. A/Sydney/5/97, Herpes Simplex Virus-1, or Urbani SARS.

The specification fails to provide scientific data and working embodiments with respect to destroying, inactivating or inhibiting growth or reproduction of viruses other than A/Sydney/5/97, Herpes Simplex Virus-1, or Urbani SARS.

Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad of experimentation to determine whether PMD is effective at treating viruses other than A/Sydney/5/97,

Herpes Simplex Virus-1, or Urbani SARS. There are various viruses containing lipid envelopes, such as HIV or Hepatitis C, where there is no known drug capable of destroying the virus. Viruses have different mechanisms by which they can produce disease and separate planning is crucial in developing an effective treatment that can target the specific mechanism for that specific disease. One of ordinary skill would have to conduct series of trials to determine the mechanism by which the virus produces disease and determine whether PMD is effective in vivo, in vitro, etc, for each distinct virus. Since Applicant has only shown the virucidal activity of PMD on three viruses out of the seemingly infinite number of viruses and no guidance was provided for any other virus, especially ones where there is no known cure, one of ordinary skill in the art would be required to conduct an undue amount of experimentation.

For the foregoing reasons, Applicant is not enabled for destroying, inactivating or inhibiting growth or reproduction of all viruses that contain a lipid envelope using PMD.

Response to Arguments

Applicant's arguments filed August 8, 2008 have been fully considered but they are not persuasive.

Applicant argues that the specification provides enablement for the destruction, inactivation, or inhibition of viruses that contain a lipid envelope.

This argument is not convincing. Applicant has described viruses such as HIV, Hepatitis, B and C as viruses that contain a lipid envelope (see the instant specification

page 4). As stated above, Applicant has not provided any data to support the inhibition of viruses such as HIV, where there is no cure. Thus, it is unclear whether PMD will function to destroy and inactivate such viruses.

Therefore, Applicants arguments of nonobviousness are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112 2nd

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 23-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 recites "A method comprising administering p-methane-3,8-diol (PMD) to destroy, inactivate growth or reproduction of a virus." However, Applicant do not describe what the method is for. The claim does not provide an active method step to distinguish the prior art over the instant invention.

For purposes of Examination, the Examiner interprets the claim to read as a method of destroying, inactivating the growth or reproduction of a virus comprising administering p-methane-3,8-diol (PMD) to a surface.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
8. Claims 23-39 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vail, III et al. (US 2004/0009245) in view of Clark(WO 01/05226).

Applicant claims a method of destroying, inactivating the growth or reproduction of a virus containing a lip envelope comprising administering p-methane-3,8-diol (PMD).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Vail, III et al. teach concentrated antiseptic botanical essential oils such as *Eucalyptus citriodora*, have antiviral, antibacterial, and antifungal properties (see the abstract). The concentrated vapors from the essential oils can be used to treat viruses such as influenza, herpes simplex virus, etc., which can cause Severe Acute Respiratory Syndrome (SARS) by inhalation (see the abstract, page 21 paragraphs 519, and 525-527).

Ascertainment of the difference between the prior art and the claims

Vail, III et al. teach antiseptic essential oils such as *Eucalyptus citriodora*, also have antiviral properties and can be used to viruses. However, Vail, III et al do not specifically recite the use of p-methane-3,8-diol (PMD). Further, Vail, III et al. do not teach the composition in spray form. This deficiency is cured by the teachings of Clark.

Clarke teaches antiseptic composition comprising p-methane-3,8-diol (PMD) (see the abstract). The PMD can be derived from a natural source, preferably the lemon eucalyptus plant (see page 2 paragraph 2). The PMD can be extracted in pure form, or a crude extract derived from the lemon eucalyptus plant (also called *Eucalyptus Citriodora*) (see page 2 paragraphs 2-3). The antiseptic composition of the invention can comprise PMD and a carrier (see page 2 paragraph 7). PMD can be used in an amount up to 5% by weight of the composition (see page 5 lines 1-5). PMD can be used to sanitize surfaces such as a skin surface (i.e. hand, open wound, etc), nasal passage,

glove, apparatus, etc (see page 4 paragraph 2 and claims 17 and 20-23). The PMD can be impregnated into household objects, medicine, detergents, cleansers, etc. (see page 3, paragraph 6 and page 5, paragraph 2-6). The PMD composition can be formulated as a throat lozenge, shampoo, skin spray, nasal spray, wound irrigation, cream for nasal administration and as a spray (see page 3 paragraph 6, page 4 paragraph 1 and claim 12).

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

One of ordinary skill in the art would have been motivated to treat viruses with PMD because Vail, III et al. teach treating viruses using essential oils such as, *Eucalyptus Citriodora* (or lemon eucalyptus). Further, it is known in the art that PMD is contained in *Eucalyptus Citriodora* (or lemon eucalyptus), as suggested by Clark.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to treat viruses with PMD because it is a known component in *Eucalyptus Citriodora* which is known to treat viruses.

Although Vail, III et al. do not teach additional forms of making the antiseptic composition, it is known in the art to prepare antiseptic compositions in spray form, and for therapeutic and non-therapeutic uses, as suggested by Clark.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

9. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vail, III et al. (US 2004/0009245) in view of Clarke (WO 01/05226), further in view of Lemelson (US 4,856,509).

Applicant claims a method of destroying, inactivating the growth or reproduction of a virus comprising administering p-methane-3,8-diol (PMD).

Determination of the scope and content of the prior art
(MPEP 2141.01)

Vail, III et al. teach concentrated antiseptic botanical essential oils such as *Eucalyptus citriodora* have antiviral, antibacterial, and antifungal properties (see the abstract). The concentrated vapors from the essential oils can be used to treat viruses such as influenza, herpes simplex virus, etc., which can cause Severe Acute Respiratory Syndrome (SARS), (see the abstract, page 21 paragraphs 519, and 525-527).

The disclosure of Clarke is set forth above. Specifically, Clarke teaches an antiseptic composition comprising p-methane-3,8-diol (PMD).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

Vail, III et al. and Clark combined teach the use of *Eucalyptus citriodora* (which contains PMD) for treating viruses but do not teach the application of PMD to a face mask. This deficiency is cured by the teaching of Lemelson.

Lemelson teaches improved face masks, for use in preventing the spread of disease such as colds, influenza, or viral infections, wherein a portion of the mask contains a disease or viral destroying chemical or biological agent (see the abstract and column 1 lines 35-40, column 2 lines 6-10). The mask can be provided with a filter element with a removable capping sheet that contains the disease or viral destroying chemical or biological agent (see column 3 lines 10-44 and column 8 lines 14-23). The releasable medication may be in the form of an antibiotic, antiseptic, antibacterial or virus destroying medication (see column 9 lines 4-9).

**Finding of prima facie obviousness
Rational and Motivation (MPEP 2142-2143)**

One of ordinary skill in the art would have been motivated to use a face mask containing PMD because Lemelson suggest the use of face masks containing viral destroying agents in preventing the spread of disease such as colds, influenza, or viral infections.

Thus, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use a face mask containing PMD for the purpose of preventing the spread of such viruses to other individuals.

Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed August 8, 2008 have been fully considered but they are not persuasive.

Applicant argues that PMD is not present in appreciable amounts in *Eucalyptus citriodora*. Applicant relies on the teachings of journal publication Basara et al., as evidence that PMD is not present naturally in large amounts. Applicant further argues that one of ordinary skill in the art would not attribute the antiviral properties of *Eucalyptus citriodora* to PMD, since PMD is only present naturally in trace amounts.

This argument is not persuasive. First, it should be noted that Applicant admits that PMD is present in *Eucalyptus citriodora*. Second, Applicant has not specified a specific amount of PMD that should be present in the instant claim (see claim1), and thus, any amount of PMD would be an acceptable amount to meet the limitation of the instant claims.

Therefore, Applicant's arguments of nonobviousness are not persuasive.

Conclusion

10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristie L. Brooks whose telephone number is (571) 272-9072. The examiner can normally be reached on M-F 8:30am-6:00pm Est..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KB
/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616